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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,798	10/18/2000	Xavier Paliard	PP01521.101	3092

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EXAMINER	
LI, QIAN JANICE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/673,798	PALIARD, XAVIER	
	Examiner	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 10-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 10-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 May 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/17/03 has been entered.

The amendment filed on 9/26/03 has been entered. Claim 11 has been amended, and claims 29 and 30 are newly submitted. Claims 1-7 and 10-31 are pending and under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated. The arguments in 9/26/03 response would be addressed to the extent that they apply to current rejection.

Priority

This application claims benefit of priority from U.S. provisional patent application 60/082,600, and PCT/US99/08802. However, Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). In the instant case, a B lymphocyte chemoattractant has not been disclosed in U.S. provision patent application 60/082,600, therefore, the priority date for the subject matter has been established as April 22, 1999, the filing date of the PCT application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-29 are rejected under 35 U.S.C. 112 first paragraph, because the specification as originally filed does not describe the invention as now claimed. The original disclosure fails to specify the subject matter regarding "a single control sequence derived from a virus" as now claimed, and thus the subject matter is now considered to be new matter.

To the extent that the claimed subject matter is not sufficiently described in the instant disclosure, claims 11-29 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way

as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

In the response accompanying the amendment, applicants indicate, "Support for this amendment can be found throughout the specification as filed, for instance in the Examples". In response, it is noted although the examples of instant application teach a plasmid comprising a CMV promoter/enhancer, the specification fails to teach the genus of viral derived control sequences in general, and it fails to discuss using only one single control sequence in a plasmid construct. In fact, the plasmid vector disclosed in the specification contains at least two control sequences, i.e. the CMV promoter and CMV enhancer. It is noted that the newly added term is not limited to a transcription control sequence (promoter), it encompasses any control sequence such as a stop codon, and a poly-A control sequence derived from any virus. Accordingly, the specification fails to provide sufficient support for what is now claimed.

MPEP 2163.02 teaches that "WHENEVER THE ISSUE ARISES, THE FUNDAMENTAL FACTUAL INQUIRY IS WHETHER A CLAIM DEFINES AN INVENTION THAT IS CLEARLY CONVEYED TO THOSE SKILLED IN THE ART AT THE TIME THE APPLICATION WAS FILED...IF A CLAIM IS AMENDED TO INCLUDE SUBJECT MATTER, LIMITATIONS, OR TERMINOLOGY NOT PRESENT IN THE APPLICATION AS FILED, INVOLVING A DEPARTURE FROM, ADDITION TO, OR DELETION FROM THE DISCLOSURE OF THE APPLICATION AS FILED, THE EXAMINER SHOULD CONCLUDE THAT THE CLAIMED SUBJECT MATTER IS NOT DESCRIBED IN THAT APPLICATION". MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW

MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added). However, the specification is completely silent with respect to the control sequences generated from viruses, and it fails to teach why a single promoter plasmid construct is an inventive concept. Thus, the amendment is a departure from or an addition to the disclosure of the application as filed, accordingly, it introduces new matter into the disclosure.

For reasons set forth above, the amendment filed 9/26/03 is objected to under 35 U.S.C. §132 because it introduces new matter into the disclosure. 35 U.S.C. §132 states that no amendment shall introduce new matter into the disclosure of the invention. Applicant is required to cancel the new matter in the reply to this Office Action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite because of the claim recitation, "a single control sequence derived from a virus". There many different control sequences in a virus, it is unclear which control sequence the claim refers to, and thus the metes and bounds of the claims are uncertain. Moreover, since the instant specification uses a plasmid comprising at least two control sequences, i.e. CMV promoter and enhancer,

this contradicts the claims. For the interest of a compact prosecution and for the purpose of applying prior art, the term has been interpreted as one single promoter for transcription in a genetic construct.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5-7, 10-22, 25-31 are rejected under 35 U.S.C. 102(e) as being anticipated by *Garzino-Demo et al* (US 6,569,418).

Garzino-Demo et al teach an immunogenic composition comprising a plasmid encoding an immunogen, and a BLC or a polynucleotide encoding BLC (e.g. Fig. 3b, column and column 7, lines 33-50), wherein the immunogen is a viral immunogen such as HIV gag (column 16, line 63), or a tumor immunogen (column 18, line 16).

Garzino-Demo et al teach a method of enhancing immune response to a viral immunogen in a mammal comprising intradermal or intramuscularly administering the immunogenic composition (column 27, lines 24-32) in a pharmaceutically acceptable carrier (column 25, line 31), wherein the antigen could be administered before, during, or after the administration of the chemokine in sufficient temporal proximity (e.g. column

7, lines 7-17), wherein the plasmid expressing the viral immunogen comprising a single promoter CMV (column 16, lines 38-42), wherein the chemokine is MIP1-α (column 7, line 29) or BLC (column 7, line 42). *Garzino-Demo et al* also teach that BLC induces a humoral (antibody) response, while macrophage derived chemokines induce mostly cellular response (column 1, lines 45-54). Accordingly, *Garzino-Demo et al* anticipate instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 4, 11, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Garzino-Demo et al* (US 6,569,418), in view of *Jolly et al* (US 6,297,048).

Garzino-Demo et al teach an immunogenic composition comprising a plasmid encoding a viral immunogen and methods of using such for enhancing vaccination, wherein the immunogen is a hepatitis antigen (column 18, line 14), *Garzino-Demo et al* do not particularly teach a hepatitis C virus non-structural polypeptide.

Jolly et al teach making and using a genetic vector encoding a hepatitis C viral antigen NS3-NS4 for inducing immune response.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods taught by *Garzino-Demo et al* by simply selecting hepatitis C NS3-NS4 antigen in the composition for immunization as taught by *Jolly et al* with a reasonable expectation of success. The ordinary skilled artisan would have been motivated to modify the claimed invention because it is within the levels of the ordinary skilled in the art to make and use a chemokine-viral immunogen composition with any antigen of interest. Thus, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Claims 11-13, 16, 17, 21, 25, and 27-29 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over *Hurwitz et al* (US 5,846,546).

Hurwitz et al teach an immunogenic composition comprising a bi-functional plasmid vector encoding HIV envelope protein-coding region (abstract), and further comprising a polynucleotide encoding a chemokine such as MIP1α (2nd paragraph column 29). The composition is suitable for vaccination in mammals including humans (2nd paragraph column 1), and could induce both antibody and cytotoxic T lymphocyte response (column 2, lines 46-55). A pharmaceutical carrier is taught throughout the teachings in columns 28-31. The bi-functional viral vector comprises one promoter (CMV, viral derived control sequence as used by the instant applicants) for expression in mammalian cells, and another promoter for preparation of viral vector (column 4, lines 41-45).

In the response to the previous rejection under § 102 by *Hurwitz et al*, applicants argue that claims have been amended as directed to administering a plasmid containing only a single expression control sequence whereas, Hurwitz discloses a bi-functional plasmid that contains at least two expression control elements, and accordingly anticipation cannot be established.

In response, the rejection has been modified accordingly to address the amended claim. The claimed invention is obvious over *Hurwitz et al* because *Hurwitz et al* clearly teach they are providing a new plasmid, wherein only one promoter is required for expressing the antigen-chemokine protein in mammalian cells (column 4, lines 41-45). *Hurwitz et al* teach that the CMV promoter is powerful for expression of heterologous genes in mammalian cells. Only when using the plasmid as a shuttle plasmid for preparation of recombinant vaccinia virus, the other promoter in the plasmid is functional for expression control of the virus, thus, virtually only one transcription control sequence is operably linked to a sequence encoding a viral immunogen for expressing the immunogen in mammalian cells, and the other promoter would not function in mammalian cells (column 9, lines 3-27). Further, the new bi-functional plasmid is relative to previous single functional plasmid which is apparently well known in the art. *Hurwitz et al* teach the advantage of the bi-functional plasmid (relative to the single functional plasmid, paragraph bridging columns 8-9)

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the plasmid taught by *Hurwitz et al*, or use a conventional single-functional plasmid for immunogen expression with a reasonable

expectation of success. Given the numerous types of vectors available in the art at the time of the effective filing date, this limitation would fall within the bounds of optimization. Thus, the claimed invention as a whole was clearly *prima facie* obvious in the absence of evidence to the contrary.

Claims 11-21 and 23-29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Hurwitz et al* (US 5,846,546) as applied above to claims 11-13, 16, 17, 21, 25, and 27-29, and in view of *DeVico et al* (US 6,214,540) for reasons of record.

In 9/26/03 response, applicants' arguments are drawn to the newly added claims 30 and 31, which were not included in the rejection. Applicants also presented the same argument as in Hurwitz rejection, which have been addressed above, and will not be reiterated.

Claims 11-13, 16, 17, 21, 27, and 29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Chandrashekar et al* (US 6,383,774) in view of *Hurwitz et al* (US 5,846,546) for reasons of record.

In 9/26/03 response, applicants' arguments are drawn to the newly added claims 30 and 31, which were not included in the rejection. Applicants also presented the same argument as in Hurwitz rejection, which have been addressed above, and will not be reiterated.

Conclusion

No claim is allowed.

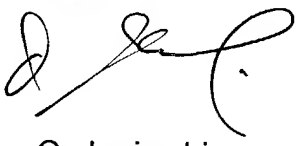
Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Amy Nelson** can be reached on 571-272-0804. The fax numbers for the organization where this application or proceeding is assigned are **703-872-9306**.

Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is **703-308-0196**.

JANICE LI
PATENT EXAMINER



Q. Janice Li
Patent Examiner
Art Unit 1632

QJL
January 22, 2004